NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA

0408 '96 JUN 23 P2:15

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Excel™ *Diet Formula Exercise & Diet Plan*** **Product #52499** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure-function claim for **Diet Formula Exercise & Diet Plan** is as follows:

(Statement 1) The Excel™ Diet Formula provides a patented combination of amino acids, vitamins, and minerals as part of a sensible diet and exercise program. Excel™ Diet Formula contains the amino acids DL-Phenylalanine, L-Glutamine, L-Tyrosine, and %-Hydroxytryptophan. Chromium is an essential trace mineral with roles in carbohydrate and fat metabolism. Pyridoxal-5-phosphate is the coenzymatic form of Vitamin B-6, which is important for function of enzymes.

(Statement 2) The Excel™ Diet Formula Plan incorporates the steps needed to achieve the lean hard body you've always wanted. By following the complete program, you will have a positive change in your appearance, increased energy and a greater sense of well-being.

(Statement 3) How Excel™ Diet Formula Works: Excel™ Diet Formula normalizes the "Reward System" in your brain by maintaining normal levels of neurotransmitters involved in control of eating behavior. When normal neurotransmitter function is maintained, food intake can be controlled, and carbohydrate binging and craving can be reduced. In a preliminary human clinical trial, Excel™ Diet Formula promoted weight loss at levels comparable to those shown in other clinical trials, and subjects had reduced carbohydrate binging and craving. In another preliminary human trial, Excel™ Diet Formula, when administered after a weight loss program, reduced the amount of weight regain in a two-year time period. Excel™ Diet Formula is safe to use.

97S-0162

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I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International., Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 3rd day of June, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: L R Bucci

DR. LUKE R. BUCCI
Vice President of Research

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

STRUCTURE/FUNCTION CLAIMS

NUTRIENT: DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5-Hydroxytryptophan, L-Carnitine, Chromium, B6

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Document Name: sf01exdf.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): Excel 52499 Diet Formula 120t
Excel Diet Formula Exercise & Diet Plan

NUTRIENT AMOUNTS:

Supplement Facts

Serving Size 4 capsules daily
Servings Per Container: 30

Amount Per Serving		% Daily Value*
Vitamin B6 (as pyridoxal-5-phosphate)	20mg	1000%
Chromium (as picolinate)	133mcg	110%
DL-Phenylalanine	1800mg	**
L-Tyrosine	200mg	**
L-Glutamine	100mg	**
L-5-Hydroxytryptophan	4mg	**
L-Carnitine (as tartrate)	40mg	**

* Reference Daily Intakes (RDI)
** Daily Value not established

Other ingredients: Dicalcium phosphate, cellulose, stearic acid, silica, magnesium stearate and cellulose based coating.

STRUCTURE/FUNCTION CLAIM:

Bottle:
The EXCEL™ DIET FORMULA provides a patented combinaiton of amino acids, vitamins, and minerals as part of a sensible diet and exercise program. EXCEL™ DIET FORMULA contains the amino acids DL-phenylalanine, L-Glutamine, L-Tyrosine, and 5-Hydroxytryptophan. Chromium is an essential trace mineral with roles in carbohydrate and fat metabolism. Pyridoxal-5-phosphate is the coenzymatic form of vitamin B6, which is important for the function of enzymes.

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Exercise & Diet Plan:

The EXCEL™ DIET FORMULA plan incorporates the steps needed to achieve the lean hard body you've always wanted. By following the complete program, you will have a positive change in your appearance, increased energy and a greater sense of well-being.

HOW EXCEL™ DIET FORMULA WORKS:
EXCEL™ DIET FORMULA normalizes the "Reward System" in your brain by maintaining normal levels of neurotransmitters involved in control of eating behavior. When normal neurotransmitter function is maintained, food intake can be controlled, and carbohydrate binging and craving can be reduced. In a preliminary human clinical trial, EXCEL™ DIER FORMULA promoted weight loss at levels comparable to those shown in other clinical trials, and subjects had reduced carbohydrate binging and craving. In another preliminary human trials, EXCEL™ DIET FORMULA, when administered after a weight loss program, reduced the amount of weight regain in a two year time period. EXCEL™ DIET FORMULA is safe to use.

C S R Blum 5/1/95

Approved by / Date

REFERENCES:

EXCEL™ DIET FORMULA TABLETS:

Amino Acids:

1. Blum K, Trachtenberg MC, Cook DW. Neuronutrient effects on weight loss in carbohydrate bingers: an open clinical trial. *Curr Ther Res* 1990; 48(2):217-233.
2. Blum K, Sheridan PJ, Wood RC, Braveman ER, Chen TJH, Cull JG, Comings DE. The D2 dopamine receptor gene as a determinant of reward deficiency syndrome. *J Royal Soc Med* 1996; 89:396-400.
3. Blum K, Cull JG, Braverman ER, Comings DE. Reward deficiency syndrome. *American Scientist* 1996; 84:132-145.
4. Blum K, Cull JG, Chen TJH,Garcia-Swan S, Holder JM, Wood R, Braverman ER, Bucci LR, Trachtenberg MC. Clinical evidence for effectiveness of PhenCal™ in maintaining weight loss in an open-label, controlled, 2-year study. *Curr Ther Res* 1997; 58(10):745-763.
5. Blum K, Holder JM. *The Reward Deficiency Syndrome. A Biogenic Model*, Amereon House, Mattituck, NY, 1997.

Chromium:

1. Mertz W. Chromium - an overview, in *Chromium in Nutrition and Metabolism*, Shapcott D, Hubert J, Eds., Elsevier/North Holland Biomedical, Amsterdam, 1979, 1-14.

2. Saner G. The metabolic significance of dietary chromium. *Nutr Int* 1986; 2(4):213-220.
3. Offenbacher EG, Pi-Sunyer FX. Chromium in human nutrition. *Ann Rev Nutr* 1988; 8:543-563.
4. Anderson RA. Chromium, in *Trace Minerals in Foods*, Smith K, Ed., Marcel Dekker, New York, 1988, 231-247.
5. Anderson RA. Essentiality of chromium in humans. *Sci Total Environ* 1989; 86:75-81.
6. Evans GW. The effect of chromium picolinate on insulin controlled parameters in humans, *Int J Biosocial Res* 1989; 11:163-180.
7. Stoecker BJ. Chromium, in *Present Knowledge in Nutrition*, 6th ed., Brown ML, Ed., International Life Sciences Foundation, Washington, DC, 1990, 287-293.
8. McCarty MF. The case for supplemental chromium and a survey of clinical studies with chromium picolinate. *J Appl Nutr* 1991; 43:58-66.
9. Kaats GR, Wise JA, Blum K, Morin RJ, Adelman JA, Craig J, Croft HA. The short-term therapeutic effect of treating obesity with a plan of improved nutrition and moderate caloric restriction. *Curr Ther Res* 1992; 51(2):261-274.
10. Evans GW, Pouchnik DJ. Composition and biological activity of chromium-pyridine carboxylate complexes, *J Inorg Biochem* 1993; 49:177-187.
11. Mertz W. Chromium in human nutrition: a review. *J Nutr* 1993; 123:626-633.
12. Nielsen FH. Chromium, in *Modern Nutrition in Health and Disease*, Vol. 1, 8th ed., Shils ME, Olson JA, Shike M, Eds., Lea & Febiger, Philadelphia, PA, 1994, 264-268.

Exercise & Diet Plan:

1. Kuczmarski RJ, Flegal KM, Campbell SM, Johnson CL. Increasing prevalence of overweight among US adults: the National Health and Nutrition Examination Surveys, 1960 to 1991. *JAMA*, 1994; 272:205-211.
2. Pi-Sunyer FX. Obesity, Ch 59 in *Modern Nutrition in Health and Disease*, Vol. 2, 8th ed., Shils ME, Olson JA, Shike M, Eds., Lea & Febiger, Philadelphia, PA, 1994, 984-1006.
3. Wilmore JH, Costill DL. Obesity, diabetes, and physical activity, in *Physiology of Sport and Exercise*, Human Kinetics, Champaign, IL, 1994, 490-510.
4. Bray GA. Drug treatment of obesity. Presented at St. Mark's Hospital, Salt Lake City, UT, Sep. 1996.
5. Wolf AM, et al. The cost of obesity: the US perspective. *Pharmacol Econ*, 1994; 5(suppl 1):34-37.
6. Sanders TAB, Woolfe R, Rantzen E. Controlled evaluation of slimming diets: use of television for recruitment. *Lancet* 1990; 336:918-920.
7. Weinsier RL, Johnston MH, Doleys DM, Bacon JA. Dietary management of obesity: evaluation of the time-energy displacement diet in terms of its efficacy and nutritional adequacy for long-term weight control. *Br J Nutr* 1982; 47:367-379.

Weider Nutrition Group
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8. Weinsier RL, Wadden TA, Ritenbaugh C, Harrison GG, Johnson FS, Wilmore JH. Recommended therapeutic guidelines for professional weight loss programs. *Am J Clin Nutr*, 1984; 40:865-872.
9. Pi-Sunyer FX. Obesity, in *Conn's Current Therapy*, Rackerl RE, Ed., WB Saunders, Philadelphia, PA, 1985.
10. Lissner L, Levitsky DA, Strupp BJ, Kalkwarf HJ, Roe DA. Dietary fat intake and the regulation of energy intake in human subjects. *Am J Clin Nutr*, 1987; 46:886-892.
11. Morgan SL. Rational weight loss programs: a clinician's guide. *J Am Coll Nutr*, 1989; 8:186-194.
12. Wilson MA. Treatment of obesity. *Am J Med Sci* 1990; 299:62-68.
13. Kendall A, Levitsky DA, Strupp BJ, Lissner L. Weight loss on a low-fat diet: consequence of the imprecision of the control of food intake in humans. *Am J Clin Nutr*, 1991; 53:1124-1129.
14. Johnson HL, Van Loan MD, Belko AZ, Barbieri TF, Mayclin PL, Virk SP. Brief communication: changes in thermogenesis and caloric efficiency with high and normal protein-reducing diets in women. *J Am Coll Nutr* 1992; 11(3):263-266.
15. Pate RR, Pratt M, Blair SN, Haskell WL, Macera CA, Bouchard C, Buchner D, Ettinger W, Heath GW, King AC, Kriska A, Leon AS, Marcus BH, Morris J, Paffenbarger RS, Patrick K, Pollock ML, Rippe JM, Sallis J, Wilmore JH. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA* 1995; 273(5):402-407.
16. Henson LC, Poole DC, Donahoe CP, Heber D. Effects of exercise training on resting energy expenditure during caloric restriction. *Am J Clin Nutr* 1987; 46:893-896.
17. Zuti WB, Golding LA. Comparing diet and exercise as weight reduction tools. *Phys SportsMed* 1976; 4:49-53.